APR 12 2004

Section E – 510K Summary

Submitter: MedSolve LLC
1140 Highland Avenue #222
Manhattan Beach, CA 90266
(310) 939-9088

Contact: Susan McConnell
4635 Gershwin Place
Woodland Hills, CA 91364
(818) 223-8537
(818) 223-8579 FAX

Name of Device: MedSafe™ System Inserter

Generic Device Name: Syringe Insertion Device

Classification: General Hospital, 21 CFR880 Type II

Product Code	KZH
Regulation Number	Section 880-6920
Classification Name	Introducer, Syringe Needle

Establishment Registration: MedSolve LLC has not yet obtained an Establishment Registration Number.

Manufacturing Facility: Manufacturing location has not yet been determined.

Performance Standards: No performance standards applicable to this device have been establish under Section 514 of the Act. The device is in compliance with the following voluntary standards:

1. 21 CFR 820, Code of Federal Regulations
2. 21 CFR 801 or 809, Code of Federal Regulations
3. EN46001, Quality Systems – Medical Devices – Particular Requirements for the Application of EN ISO 9001
4. 49 CFR 178.603, Department of Transportation (DOT) Drop Test
5. ISO 15223, Medical Devices – Symbols to be used with medical device labels, labeling, and information to be supplied.

Labeling: Draft labeling is contained in the submission.

Product Description:

This device is used in conjunction with a commercially available syringe to aid in the insertion of the syringe needle.

The device is constructed of thick walled rigid polycarbonate injection molded components, and a spring, that are permanently assembled within a housing. The devices are provided bulk non-sterile to the user.

The user fills a standard syringe and places it in the device. The user positions the device against the injection site. The safety feature is unlocked by rotating the moving carrier. The insertion spring is activated by pressing the device against the skin at the injection site. This spring advances the syringe such that the needle penetrates the skin. The user dispenses the medication by depressing the syringe plunger.

Two 'legs' snap over the plunger at the end of the injection stroke to capture the syringe plunger. The device is disposed of in appropriate sharps containers according to local, state, and Federal regulations.

Predicate Device: Palco Inject-Ease, 510K Number: K872233

Intended Use of the New Device: Single-use non-sterile device intended to aid in the insertion of a commercially available syringe. The Safety feature prevents needle reuse.

Substantial Equivalence:

Technologically, both insertion devices are spring driven devices that require the user to load the syringe into the housing, and then insert the syringe needle into the patient injection site.

The difference between the new device and the predicate disposal device is that the MedSafe™ Inserter inserts the syringe needle by pressing the device against the insertion site rather than requiring the user to push a trigger. A locking feature on the MedSafe™ Inserter device prevents accidental activation.

Another difference between the new device and the predicate insertion device is that there is no requirement for the user to set insertion depth. Model 200 of the MedSafe™ System Inserter is designed for the specific manufacturer's syringe design, syringe size, and needle length specified. The predicate device requires the user to add a 'spacer' to adjust needle penetration depth.

Another difference between MedSafe™ and Inject-Ease is that MedSafe™ is designed as a single use disposable device rather than a reusable device. Thus, the MedSafe™ System Inserter does not require removal of the syringe for disposal nor does it require cleaning.

The comparison table indicating the device is substantially equivalent[1] to the predicate device is shown below:

Feature	**MedSafe™ System Inserter K032848**	**Inject-Ease K872233**
Intended Use	Aid in the insertion of a commercially available syringe into patient	Aid in the insertion of a commercially available syringe into patient
Users	Personal Injections Hospitals Clinicians	Personal Injections Hospitals Clinicians
Compatible Syringes	Various by model	Various by model
Insertion Mechanism	Metal Spring	Metal Spring
Housing material	Rigid Plastic – opaque	Rigid Plastic - opaque
Sterility	Non Sterile	Non Sterile
Disposal Method for used syringe/needle	Entire device is discarded in sharps container.	Syringe is manually removed and discarded in sharps container.
Biocompatibility	Accessory Device	Accessory Device

Confidentiality: This submission and information contained in this submission and its attachment is considered confidential, proprietary information of MedSolve LLC and a trade secret until such time as the Company distributes such information publicly.

[1] The term "substantially equivalent" as used in this submission is intended to convey only a determination of substantial equivalence pursuant to the requirements of the Federal Food and Drug and Cosmetic Act. It is not intended to have any relation in determining what is patentable or on the resolution of patent infringement suits or on other patent matter.

Applicable provisions of the Freedom of Information Act govern the release of information contained herein and pertinent FDA regulations contained in 21 CFR, Parts 20 and 800. Should the FDA contemplate release of any information contained herein, the Company hereby requests prior notice to any such release, consistent with 21 CFR 20.15 and other pertinent sections affording similar rights.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 12 2004

MedSolve Technologies LLC
C/O Ms. Susan McConnell
Principal
Susan McConnell
4635 Gershwin Place
Woodland Hills, California 91364

Re: K032848
Trade/Device Name: MedSafe™ System Inserter
Regulation Number: 880.6920
Regulation Name: Syringe Needle Introducer
Regulatory Class: II
Product Code: KZH
Dated: February 19, 2004
Received: February 20, 2004

Dear Ms. McConnell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

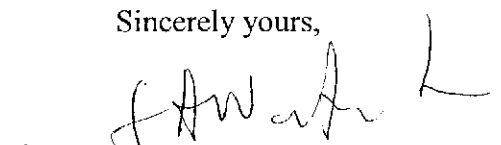
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-5618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K032848

Section D – Statement of Indications for Use

Applicant: MedSolve LLC

510 (K) Number: **K032848**

Device Name: MedSafe™ System Inserter

Indications for Use:

Single-use non-sterile device intended to aid in the insertion of a commercially available syringe. The Safety feature prevents needle reuse.

PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED

________ Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____________ or Over-The-Counter Use ____/____
(Per 21 CFR 801)

[signature] for ADW 4/8/04
(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K032848